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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,029	11/07/2001	Roger Wayne Davies	9013-36	9634

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EXAMINER	
AKHAVAN, RAMIN	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Appt 04/05/04

Office Action Summary	Application No.	Applicant(s)	
	09/936,029	DAVIES ET AL.	
	Examiner	Art Unit	
	Ray Akhavan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2004* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election filed 02/10/2004, in response to a restriction requirement is acknowledged. However, upon further consideration of the claims, a revised restriction requirement has been deemed appropriate. The following requirement supersedes the previous restriction requirement. Therefore, Applicant is required to elect a group from the following selection of groups.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372. This application contains the following inventions or group of inventions that are not so linked as to form a single inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, in response to this action applicant is required to elect a single invention to which the claims must be restricted. The groups are as follows:

I. Claims 1-8, drawn to method using a polynucleotide fragment comprising protein kinase C (PKCγ) type I in manufacture of a medicament for treating a neurodegenrative disorder.

II. Claims 9-17, drawn to method using a polypeptide fragment comprising protein kinase C (PKCγ) type I in manufacture of a medicament for treating a neurodegenrative disorder.

III. Claims 18-31, drawn to a method of testing animals for mutation in the PKCγ gene.

IV. Claim 32-33, drawn to a method of producing animal models.

V. Claim 34, drawn to a method treating degeneration of the nervous system in a subject using a polynucleotide fragment encoding a PKC type I protein.

VI. Caim 35, drawn to treating degeneration of the nervous system in a subject using a PKC type I protein.

VII. Claim 36, drawn to a method of gene therapy using a polynucleotide fragment encoding the PKC type I protein.

VIII. Claim 37, drawn to identification of compounds for use in treatment of neurodegenerative disorders using PKC type I protein.

IX. Claims 38-42, drawn to compositions of antibodies against PKCγ polypeptide epitopes.

X. Claim 43, drawn to a method of treatment using antibodies against PKCγ, to prevent, delay, or inhibit degeneration of the nervous system.

XI. Claim 44, drawn to a method of diagnosis of neural degenerative disorders in humans, using antibodies against PKCγ.

Applicant is allowed the first appearing composition (i.e. Group IX), first appearing method of using said composition and method of making said composition. Therefore if applicant elects group IX, then group X will be included in examination. The inventions listed in Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1, because there is no unity of invention under PCR Rule 13.2 which states that unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features (i.e. technical features that define a contribution which each of the inventions considered as a whole makes over the prior art). The inventions listed above lack the same or corresponding technical features for the following reasons:

Group I and II do not share a special technical feature because the former is drawn to a method of manufacturing a medicament for treatment using a polynucleotide fragment, while the latter is drawn to a method manufacturing a medicament for treatment using a polypeptide fragment. While it may be true that in each case the nucleic acid or protein are drawn to PKC

type I, each method will inherently involve different modalities in manufacturing a medicament. In short, there is not structural to function correlation as between a nucleic acid fragment and a protein fragment. Therefore, Group I would inherently have a different special technical feature as compared to Group II.

Groups I and II do not share a special technical feature as compared to Group III because the former are drawn to manufacturing a medicament while the latter is drawn to a method of testing for a mutation in PKCγ gene. There is no shared special technical feature between the methods of manufacture and method of testing, because the special technical feature in methods for manufacture would include biologically and procedurally distinct steps as compared to method of testing for a mutation. For example, manufacturing a medicament would require quality and effectiveness features simply not present in merely detecting a mutation.

The special technical feature of Group IV is production of animal models, which would not be required for the method of treatment in Group I or II, nor the method of identifying gene mutations in Group III.

Group V is drawn to a method of treatment of degeneration of the nervous system using polynucleotide fragments. This group would require special technical features not shared by any other group, because a method of treatment inheres vagaries such as toxicity, targeting, potential side effects and dosage response. None of the other groups would share Group V's special technical feature, save perhaps Group VI.

Group VI is drawn to a method of treatment of degeneration of the nervous system using polypeptide fragments. While the special technical feature in this group would have to address toxicity, targeting, potential side effects and dosage response, this group would have a distinct

technical features as compared to the preceding, because the special technical features for using proteins versus nucleic acids would be different, as there is no structure/function correlation between the nucleic acids and the proteins encoding PCK type I, in a *method of treatment*.

Group VII is drawn to gene therapy, which is perhaps one of the most problematic areas of biology and medicine. As such Group VII would inhere a special technical feature not shared with any of the other groups (e.g. transformation efficiency, delivery to target cells/tissue, integration into non-target genes resulting in unintended consequences).

The special technical feature for Group VIII is identifying compounds for treatment of neurodegenerative disease. The method of identifying such compound would not in and of itself be necessary to practice either Groups I-VII. The steps required for identification would not be present, for example, in a method manufacturing a medicament, in a method of treatment or in using antibodies. Thus, the special technical feature is distinct as compared to the preceding or subsequent groups.

Group IX is drawn to antibodies raised against PKCγ epitopes. This is not an advancement over the art, as it is commonly known in the art that once a polynucleotide sequence – thus polypeptide sequence – is known, it would be remedial to produce antibodies to said peptide or fragments thereof.

Group X and XI do not share a special technical feature with any of the preceding groups nor between each other. The former is directed to the special technical feature of treating nervous system degeneration using antibodies of Group V that would inherently involve steps and applications (e.g., *in vivo*) different from those that would inhere in Group VII (e.g., *in vitro*). Furthermore neither group shares any special technical feature with the methods of

Groups I-VII. As noted above, if Group IX were elected then X would be included in granting applicant the first appearing composition and the first appearing method of use.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR .17(i).

Conclusion

Claims are subject to a new restriction requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Akhavan whose telephone number is 703-305-4454. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

GERRY LEFFERS
PRIMARY EXAMINER